

**REVIEW STUDY ON LEFT ATRIAL APPENDAGE OCCLUSION
AND CURRENT IMPLANT DEVICES**

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**REVIEW STUDY ON LEFT ATRIAL APPENDAGE OCCLUSION
AND CURRENT IMPLANT DEVICES**

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SUMMARY

Stroke and heart-related diseases are one of the leading causes of deaths in United States. There are many factors that may cause stroke, and left atrial appendage coagulation is one of them. Left atrial appendage coagulation is a coagulation of blood inside the left atrial appendage caused by atrial fibrillation, not rhythmical contraction of your heart muscle. For left atrial appendage, not like other heart defects, anti-coagulant currently is only solution to solve this problem. There isn't any implant device solution specific for left atrial appendage occlusion. However, there are some devices that are currently going through FDA approval process. These are Watchman and Lariat. According to interviews performed with cardiac specialists throughout Atlanta, they are emphasizing three major factors. They are stability, customizability, and full occlusion. Limitations of Watchman and Lariat are customizability and full occlusion. To satisfy all three factors and to improve from Lariat and Watchman, Flow Medical has come up with innovative left atrial appendage occlusion balloon.

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CHAPTER 1

ATRIAL FIBRILLATION

Statistics & Definition

There are four million people suffering from atrial fibrillation. This number is projected to reach 12 to 16 million by the time of 2050 [1]. If these statistics are considered economically, the medical expense is projected to reach market value of 22.8 billion.

Among all the diseased conditions related to irregularly timed contraction, atrial fibrillation is the most common one. Frequently, atrial fibrillation gives an excessive load on the left atrial appendage, and it leads to an enlargement of the left atrial appendage.

By definition, atrial fibrillation patients have irregular contractions of their heart muscle. This is caused due to irregularly synchronized signals on different nodes of the heart. This irregular contraction of the heart, atrial fibrillation, may cause some serious problems. Left atrial appendage coagulation is one of them.

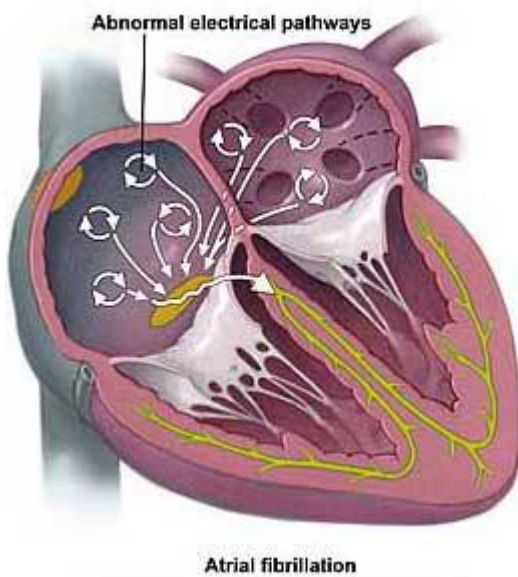


Figure 1. Atrial Fibrillation. By definition, atrial fibrillation patients have irregular contractions of their heart muscle. This is caused due to irregularly synchronized signals on different nodes of the heart.

CHAPTER 2

LEFT ATRIAL APPENDAGE

STRUCTURE

The left atrial appendage is located on left side of your left atrium. It is a finger like projection and comes in various shapes, and its length is about 2-4 cm pointing toward the apex.

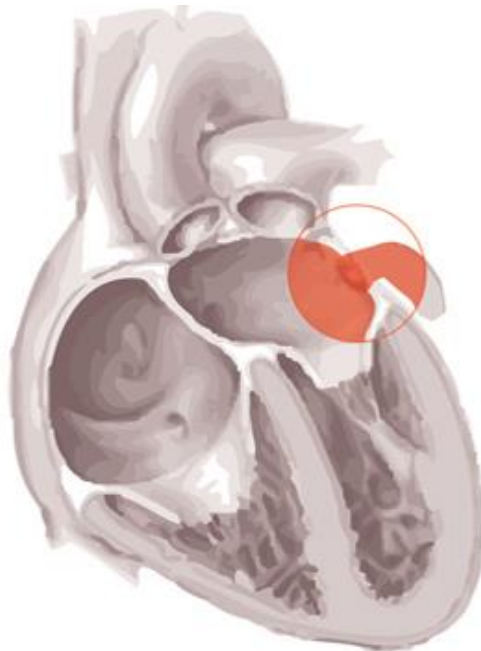


Figure 2. The left atrial appendage is located on left side of your left atrium. It is a finger like projection and comes in various shapes, and its length is about 2-4 cm pointing toward the apex.

COAGULATION & STROKE

For patients with left atrial appendage coagulation, the blood flow into the left atrial appendage, and it does not come back out due to lack of contractions. After some amount of time, the arrested blood will get clogged inside the left atrial appendage. The coagulation of blood is formed. This small coagulation, in the size of left atrial appendage, will escape out of the left atrial appendage. It may travel through different vessels.

As this small piece of coagulation is traveling through the system, it may get stuck in different vascular systems such as heart, brain, and vessels. It may be developed to a serious stroke by blocking the blood flow on whatever region that it settles on. If atrial fibrillation is left untreated, risk of stroke of those individuals increases as they age. According to statistics, 15% of strokes are caused by atrial fibrillation [2]. For patients who are 70 years old and older, more than 20 to 25% of strokes are caused by atrial fibrillation [3].

CHAPTER 3

CURRENT SOLUTION

ANTI-COAGULANTS

In the medical industry today, the only used to treat atrial fibrillation is anti-coagulant. However, the average age of atrial fibrillation is 75 years old [4]. This age factor makes anti-coagulants a very dangerous solution. A simple paper cut may be turned into a catastrophic emergency if the patient is on coagulants because the blood flow will not be able to be stopped. If patients fall from stairs or any kind of internal bleeding, this may be lead to serious event as well.

Warfarin, an active ingredient in rodenticide agents, is the current standard treatment to decrease the risk of stroke in atrial fibrillation patients. The mechanism of this anticoagulant is working by inhibiting various clotting factors in the blood stream to prevent formation of clots. For entire atrial fibrillation population, only 70% of those population are considered ideal candidates for Warfarin [5]. This already leaves out 30% of atrial patients in potential risk of stroke.

On top of this, due to potential complications from a blood thinning medicine and multiple risk factors, the percentage has been cut down to as few as 25% of atrial fibrillation patients.

However, there are serious side effects with using anti-coagulant. Anti-coagulants fail to approach the heart of the matter. For this reason, there are two devices out there, which are approaching the heart of the problem, rather than taking alternative route to inhibit the matter. These two devices are Watchman and Lariat, and these devices are under FDA approval process to become legitimate left atrial appendage occlusion devices.

WATCHMAN (INTRACARDIAC DEVICE)

The watchman is an intracardiac device that been supported by a FDA panel and looking to acquire FDA approval. The device is installed inside heart using catherization and transeptal puncture method. The material of device is made of polyethylene terephthalate (PET) and nitinol, functioning memory-shaping and occluding. After implantation, patients must take the anti-coagulant for 45 days until scar tissue forms over it increasing the occlusal and stability properties. However, even this device cannot fully occlude the region due to not enough regenerative abilities.

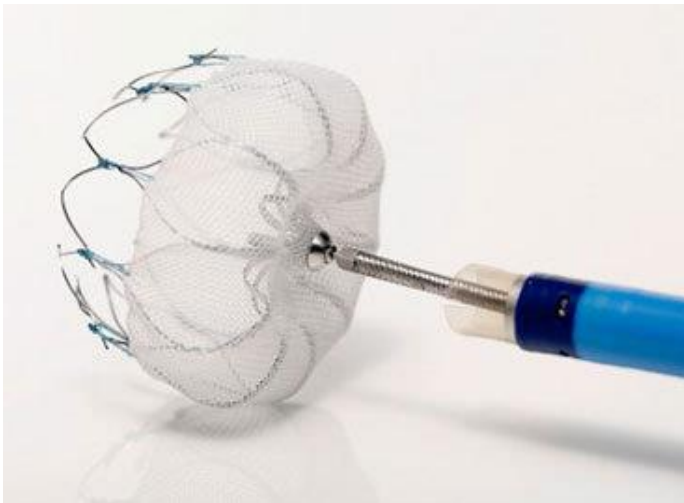


Figure 3. Watchman Intracardiac Device. The watchman is an intracardiac device made of polyethylene terephthalate (PET) and nitinol, functioning memory-shaping and occluding.

LARIAT

Lariat is actually approved by FDA for soft tissue occlusion, but not specifically for left atrial appendage. The device made of Teflon and polyester is guided towards the left atrial appendage periodically by a magnet attracting from inside the heart this device actually does provide highly accurate closure rate. The biggest problem with this device is the complexity of procedure in implanting this device. The procedure requires the electro-physician to spend a fair amount of time and effort, and it shows a steep learning curve for surgeons to learn this procedure.



Figure 6: LARIAT® delivery system (used with permission of SentreHeart).

Figure 4. Lariat. The device made of Teflon and polyester is guided towards the left atrial appendage periodically by a magnet attracting from inside the heart this device actually does provide highly accurate closure rate.

CHAPTER 4

BALLOON OCCLUSION DEVICE

As it has discussed in chapter 3, there is still room for improvement in this procedure. The only current solution, anti-coagulant, is just an alternative solution to fix the problem since there isn't any solution specific to the left atrial appendage that is FDA approved yet. As discussed on chapter 3, there are two devices that are going through the FDA approval, but they still do have problems in them. Flow Medical, founded by Arnab Chakraborty and Christine Hang, is currently working on design iteration for developing left atrial appendage occlusion device.

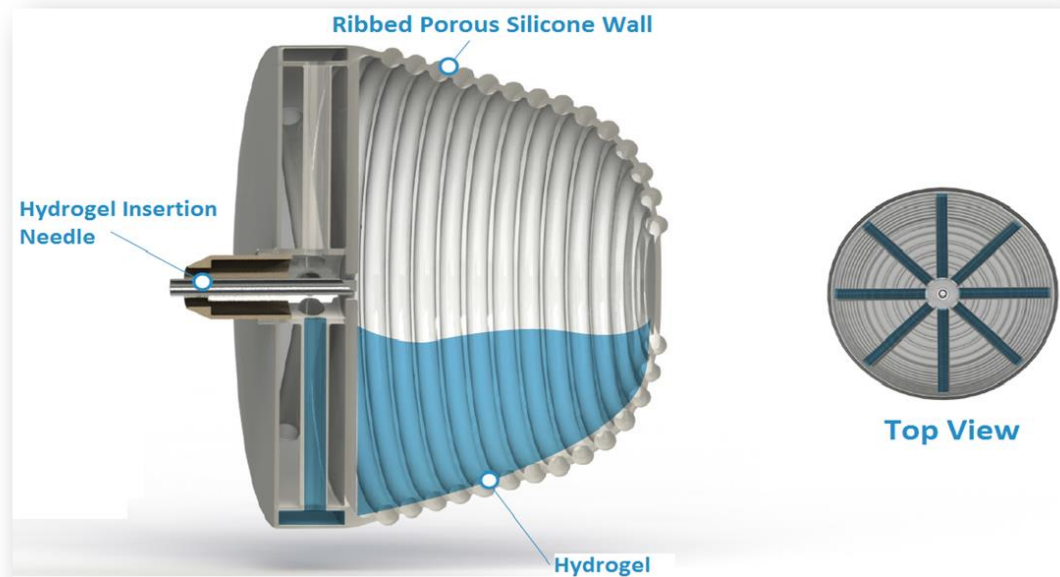


Figure 5. Flow Medical Left Atrial Occlusion Balloon. This balloon is consisted of two major compartments that will be filled up separately by Hydrogel through hydrogel insertion needle. The material is biocompatible medical silicone, and its surface will be ribbed to increase the stability in securing the position of the implant.

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